

REMARKS

Status of the Claims

Claims 2-20 are currently pending in the application. Claims 2-6, 8, 11 and 12 were rejected. Claims 7, 9 and 13 were objected to. No claims have been amended.

New claims 14-20 have been added. Applicants thank Examiner Wang for indicating that claims 7, 9, and 13 would be allowable if rewritten in independent form including all of the limitations of the base claim. New claim 14 is a combination of independent claim 12 and objected to claim 7. New claim 18 is a combination of independent claim 12 and objected to claim 9. These claims should be immediately allowable as well as their dependent claims, i.e., 15-17 and 19-20, respectively.

Rejection Under 35 U.S.C. §102(b)

Claims 2-6, 8, 11 and 12 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,254,105 to Fukuda (hereinafter "Fukuda") as evidenced by U.S. Patent No. 4,486,333 by Sebba (hereinafter "Sebba") (column 1, lines 31-47) and Menger et al. (Microscopic Observation of a Polyaphron Transforming into a Microemulsion, J. Am. Chem. Soc. 1991, 113, 5119-5120) (last three lines of left column, page 5119) to Menger et al. (hereinafter "Menger"). Applicants respectfully traverse the rejection.

In order to anticipate a claim, a reference must contain all elements of the claim. See *Hybritech v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81,

90 (Fed. Cir. 1986). Further, a single source must disclose all of the claimed elements “arranged as in the claim.” See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The law requires identity between the claimed invention and the prior art disclosure. See *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789 (Fed. Cir. 1983).

The Examiner appears to have taken the position that the multiple emulsion of Example 10 of Fukuda reads on a polyaphron. Office Action at page 5. The Examiner appears to be making this position because 1) Menger teaches that a polyaphron is also called a high internal phase ratio emulsion (Menger, page 5119, left column, first line of last full paragraph) and 2) Fukuda teaches that its w/o/w emulsion in Example 28 comprises 78% of a water/oil emulsion. However, this connection of the teachings of the references is flawed.

To be clear, Menger does not say that polyaphrons are the same as emulsions. In fact, Menger teaches that polyaphrons (despite that they may be called high internal phase ratio emulsions) are in fact not the same as an emulsion. The whole point of the Menger reference is to transform “one molecular assemblage, a polyaphron, into another, a microemulsion.” Menger, page 5119, left column, last sentence of first full paragraph. Menger teaches how polyaphrons are made and shows a photomicrograph of them in Fig. 1A on page 5119. He then teaches that water-in-oil emulsions are different in the very next paragraph, i.e., “Note that the water-in-oil microemulsion **differs in gross composition** from the oil-in-water polyaphron.” *Id.*, page 5119, right column, first full paragraph. Menger teaches that a polyaphron will transform into a microemulsion upon exposure of the polyaphron to alcohol. *Id.* Thus, Menger teaches

and recognizes that a polyaphron is not the same as an emulsion. This is consistent with the knowledge of one of ordinary skill in the polyaphron art, such as Sebba, which was recognized by Menger and also relied upon by the Examiner.

Sebba teaches substantially what Menger teaches, i.e., “too much non-polar liquid, such as the n-hexanol used in Menger, could change the environment of the aphrons and this may result in a water-in-oil type emulsion.” Sebba, col. 3, lines 30-33. Sebba teaches that polyaphrons are characterized by an “encapsulating surfactant film which surrounds each globule and acts as a barrier to coalescence, thus **clearly distinguishing the system from an emulsion.**” Sebba, col. 5, lines 63-66.

As discussed in the specification and in previous responses, a few of the key differences between a polyaphron and an emulsion as shown in the Table below.

Polyaphron	Emulsion
internal phase is surrounded by a double layer of surfactant molecules	The oil droplet is surrounded by a single layer of surfactant molecules
Can be diluted by the addition of more continuous phase without the addition of more surfactant	Cannot be diluted b/c will become unstable and coalesce and separate into two phases (oil phase and aqueous phase)

- See page 6 of the Office Action, numbered paragraph 9 citing Sebba.

Going back to Fukuda, the Examiner relies upon Example 10, which is a water-in-oil emulsion comprising beeswax, ceresine, Vaseline, etc. Fukuda, Example 10, col.

14, lines 18-32. This W/O emulsion was then dispersed in an aqueous solution and emulsified at 70 °C thereby resulting in water/oil/water emulsion. *Id.*, lines 35-50.

However, as the Examiner is no doubt aware, a chemical composition and its properties are inseparable. MPEP 2112.01. As discussed above, emulsions, such as the w/o/w emulsion in Example 10 of Fukuda is not identical or even substantially identical to the claimed polyaphron dispersion, and thus a *prima facie* case of anticipation has not been established. To be clear, Fukuda does not teach a polyaphron dispersion comprising, *Inter alia*, from about 70% to about 95% by weight based on the total weight of the polyaphron dispersion of polyaphrons having an internal phase, as presently recited.

For at least the foregoing reasons, the reference does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §103(a)

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Fukuda in view of U.S. Patent No. 4,999,198 to Barnett et al. (hereinafter “Barnett”). Applicants respectfully traverse the rejection.

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007):

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such

secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, “[a]ll claim limitations must be considered” because “all words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385. According to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR International Co. v. Teleflex Inc.*, Federal Register, Vol. 72, No. 195, 57526, 57529 (October 10, 2007), once the *Graham* factual inquiries are resolved, there must be a determination of whether the claimed invention would have been obvious to one of ordinary skill in the art based on any one of the following proper rationales:

(A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007).

Furthermore, as set forth in *KSR International Co. v. Teleflex Inc.*, quoting from *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006), “[R]ejections on obviousness grounds

cannot be sustained by mere conclusory statements; instead, there must be some articulated reasonings with some rational underpinning to support the legal conclusion of obviousness.”

Therefore, if the above-identified criteria and rationales are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because the references, alone or in combination, fail to teach or suggest all the claim elements.

Claim 10 depends from independent claim 12 and is patentable for the same reasons as independent claim 12.

As discussed in detail above, and in prior responses, Fukuda does not teach a polyaphron dispersion, and certainly does not teach all of the claim elements of independent claim 12.

The Examiner relied on Barnett for supplying this missing teaching of Fukuda. In particular, the Examiner relied on Barnett for teaching that monomers can be added to the external phase and internal phase to perform interfacial polymerization to stabilize the system. Office Action dated April 28, 2010, at pages 4-5. However, the Examiner has failed to point to the teaching in Barnett that overcomes the deficiencies of Fukuda.

Barnett does not teach anything about adding monomers to stabilize its system. The section referenced by the Examiner teaches that polymerization of the polyaphrons stabilizes the system. Moreover, the Examiner has not alleged that Fukuda’s emulsion is unstable and needs to be stabilized. Even if that were so, the Examiner has failed to establish why one of ordinary skill in the art of emulsions would look to a patent on

polyaphrons for drug delivery in an attempt to solve its stability problem. Further, Barnett recognized its own interfacial instability problems, and promptly taught one of ordinary skill in the art how to fix it. So, one of ordinary skill in the art wouldn't need to look to another reference, such as Fukuda.

The Examiner stated that "both Fukuda and Barnett are working on preparing the emulsion with high stability." Office Action at page 8, first full paragraph. However, this is incorrect. Barnett is silent on emulsion and instead is directed to transferring a substance into a medium using a polyaphron. See claim 1 of Barnett. So, again the Examiner is trying to equate an emulsion with a polyaphron when the very references cited by the Examiner distinguish emulsions from polyaphrons.

In essence, the Examiner has failed to establish how the combination of references teach or suggest all the claim elements. Moreover, the Examiner has failed to establish the requisite teachings or suggestions that would have motivated one of ordinary skill in the art to modify Fukuda's emulsion technology with Barnett's polyaphron dispersion to arrive at the claimed invention.

For at least these reasons, the Examiner has failed to establish a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending

claims. This is believed to be a complete and proper response to the Examiner's Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-3290.

Respectfully submitted,

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